

PATENT/Docket No. PC10833A
Appl. No. 10/091,202
Filing Date: March 5, 2002
Response to Office Action of March 23, 2004

REMARKS

Applicants object to the finality of the 03/23/2004 Office Action. The Office cited a new reference and made new arguments. The Office Action should not have been made final. Evans, US 6,506,785 was attached to the 03/23/2004 Final Office Action. It is believed that the rejection is not based on amendments entered by Applicant. Applicant respectfully requests the withdrawal of the finality of the 03/23/2004 Office Action. MPEP 706.07(a).

Claim 1 has been amended and claims 7-8, 11-12, 16-18, 28-29, 39, 40-41, and 43-46 have been withdrawn from consideration and deleted without prejudice to the filing of continuation/divisional applications. Claims 7-8 and 39 were previously canceled. Claims 11-12, 16-18, 41 and 43-46 were deleted as being drawn to non-elected subject matter. Claim 1 has been amended to remove non-elected subject matter.

Claims 1, 19 and 30 have been amended to further clarify the invention. Support for the amendment to claims 1, 19 and 30 can be found, for instance, at page 9, lines 5-13 of the specification. Claims 13-14 have been amended to depend from claim 19 rather than claim 1. Support for the amendment to claims 1, 19 and 30 can be found, for instance, at page 9, lines 2-4 of the specification. No new matter is added by these amendments.

With these amendments, claims 1-6, 9-10, 13-14, 19-27, 30-38, and 40-41 are pending.

Claims 13 and 14 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite; claims 1, 9-10, 13-15, 19-21, 24-27, 30-31, 33-34, and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,681,758 ("Fruthaler"); claims 1, 13-14, 19-21, 24-27, and 30-35 stand rejected under § 102(b) as being anticipated by U.S. Patent 4,118,512 (Eichelburg); claims 1, 9-10, 13-15, and 42 stand rejected under § 102(b) as being anticipated by U.S. Patent 5,824,336 ("Jans"); claims 1-6, 9-10, 13-15, 19-27, 30-37, 40, and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Eichelburg, in view of U.S. Patent 5,224,989 ("Likarova") and U.S. Patent 6,506,785 ("Evans"); and claims 1-6, 9-10, 13-15, 19-27, 30-38 and 42 stand rejected under § 103(a) as being unpatentable over Eichelburg in view of U.S. Patent 5,824,336 ("Jans").

§ 112, second paragraph, Rejection

The § 112, second paragraph, rejection of claims 13 and 14 has been overcome by the amendment of these claims to depend on claim 19 in which yeast is claimed as a palatable improving agent. Withdrawal of the rejection is respectfully requested.

§ 102(b) Rejection

The § 102(b) rejections are overcome by the present claim amendment. Specifically, none of the cited references teach compositions wherein the pharmaceutically active ingredient is carprofen. The amended claims, therefore, are novel over the references. Withdrawal of the § 102(b) rejections is respectfully requested.

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Rejections Under 35 U.S.C. § 103(a)

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143.03 for decisions pertinent to each of these criteria. [MPEP 706.02(j)].

Claims 1-6, 9-10, 13-15, 19-27, 30-37, 40 and 42 stand rejected as being unpatentable over Eichelburg, in view of Likarova and Evans. Applicants respectfully disagree with the rejection.

Applicants respectfully submit that neither the cited references nor the knowledge generally available to one of ordinary skill in the art contain the teaching, suggestion or motivation to render the claimed invention obvious as discussed *infra*, especially in light of what the Office admits.

The Office admits that Eichelburg does not teach the palatability-improving agent is artificial meat. Page 5, 03/23/2004 Final Office Action. The Office, however, states that Likarova teaches a film-forming composition suitable for veterinary medicine, where the film-forming comprises artificial meat or milk flavor in addition to other attractants and lurants. The Office then states that it would have been obvious for one of ordinary skill in the art to modify Eichelburg's oral animal medicine composition using the film-forming attractant flavors in view of the teachings of Likarova.

Eichelburg relates to compositions that concern yeast hydrolyzate oral ingesta for animals, where oral ingesta such as an animal medicament or animal food is combined with either hydrolyzates of *Torulopsis utilis* or *Saccharomyces cerevisiae*. Eichelburg states:

The prior art discloses that yeast may be employed in animal food in concentrations up to about 0.5% as a B vitamin supplement; however, when yeast is used in admixture with animal food in such low concentrations it has no effect on improving the palatability of the animal food. Applicant has established by experiments that such animal food whether dry animal food or moist animal food described in U.S. Pat. Nos. 3,119,691 Ludington et al. and 3,202,514 Burgess et al. either have minimal palatability as dry animal food or lose palatability as in the case of moist animal food, but such palatability can be greatly enhanced by the use of greater than 0.5% by weight of yeast hydrolyzate as a coating on such animal food. [Eichelburg, co. 8, line 66 to col. 9, line 11, emphasis added.]

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Eichelburg further provides: "When the yeast hydrolyzate is employed in admixtures with the ingesta, palatability will be reduced by virtue of the dilution effect of the ingesta on the yeast hydrolyzate. Consequently, slightly higher concentrations of the yeast hydrolyzate are preferred when it is combined with ingesta as an admixture." Eichelburg, col. 9, lines 22-27, emphasis added. Applicant did not find within Eichelburg the preferred amount of yeast when admixing, but Example 2 provides that 0.25 oz. of yeast was admixed 0.0125 oz of piperazine adipate. See Col. 10, lines 49-59. Moreover, Eichelburg concerns yeast, not artificial beef. When discussing a problem to be solved, Eichelburg at col. 2, lines 20-29, emphasis added, it is discussed that admixing food with beef extract does not work:

The prior art also teaches improvement in the palatability of dry animal food kibs by the addition of liquid beef extract such as beef broth or fish scrap. It has been observed, however, that even with the addition of liquid beef extracts, such as beef broth or fish scrap, to standard commercially-prepared dry animal food kibs, the resultant dry animal food kib does not have sufficient palatability to induce an animal to eat sufficient amounts of the animal food to maintain proper nutrition.

Likarova relates to a film-forming dispersion containing essentially acetyler of oxidized starch and triethylcitrate useful for surface protection of drug and food containing tablets, pellets, pills, granules or their components in crystalline form, especially those containing one or more active substances and ingredients. Likarova, col. 1, lines 10-16. Likarova states:

It is, therefore, a primary object of this invention to provide a film-forming dispersion which would effectively protect core containing active ingredient without submitting the core to undesirable contact with water for extended period of time as well as to high temperature, pressure, and aeration. The current invention concerning a novel type of protective coating avoids all these undesirable exposures while resulting in effective, desirable, safe and economical protective coating for drug and food containing articles and objects. [Likarova, col 2, lines 45-54, emphasis added).

As noted by Applicant in the Response to the preceding Office Action, Likarova's palatability agents are formed as films, not admixed with the active ingredient, as presently claimed. Likarova concerns films, which "may" contain artificial meat or milk flavor or some other attractants or lurrants for veterinary medicine. Likarova, col. 5, line 32. Likarva does not teach, motivate or suggest the use of artificial meat for anything but a coating.

When reading Eichelburg as a whole, it teaches away from the relatively low amount of yeast used in the present invention—that amount being 2% to 25% by weight—for admixing. Eichelburg concerns yeast for coating and admixing. Neither Likarova nor Eichelburg suggest that they should be combined and they both suggest coating is preferred. The general discussions therein would not suggest that one of ordinary skill in the art would so combine to give the pending invention. The references as a whole do not suggest the likelihood of success with the exact invention claimed in the pending application. The references are inappropriately being combined based on the disclosure of the pending application. *In re Vaack, supra.*

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Evans relates to the use of carprofen in mammals for the treatment and prevention of cartilage and subchondral bone injury and loss. Evans, col. 1, lines 9-12. The Office states that Likarova teaches ibuprofen tablets having an artificial flavor coated. The Office further states that it thus would have been obvious for one of ordinary skill in the art to optimize the palatable dosage form of Eichelburg and Likarova using carprofen as a medicament agent in view of the teaching of Evans with the expectation of providing an improve palatable dosage form comprising a medicament suitable for companion animal.

As already discussed, Likarova or Eichelburg do not suggest or motivate that they should be combined. The addition of Evans does not affect this reasoning. Evans does not suggest or motivate the combination of all three references. The general discussions in all references do not suggest that one of ordinary skill in the art would so combine. The references as a whole do not suggest the likelihood of success with the exact invention claimed in the pending application. Indeed, the references actually teach away from the claimed invention. The references are inappropriately being combined based on the disclosure of the pending application. *In re Vaeck, supra*. References may not merely combined to add the elements together. There needs to be motivation or suggestion to so combine with expectation of success of the combination of elements. As discussed, the references do not so motivate or suggest such a combination.

Applicants respectfully submit that the cited references do not provide the teaching, suggestion, or motivation that would lead a person of ordinary skill in the art to the claimed invention.

The Office also states that the limitation "wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 50% voluntary acceptance" in claims 2-6 is inherent because Eichelburg teaches the use of the same materials to obtain the same result desired by the applicant. Claim 1 concerns palatable agents where the agent is artificial beef. The Office states that Eichelburg does not teach the palatability-improving agent is artificial beef. 03/23/2004 Final Office Action, page 5. Hence, Eichelburg cannot teach the use of the "same materials" as claims 2-6. Applicant respectfully requests the withdrawal of this rejection.

Claims 1-6, 9, 10, 13-15, 19-27, 30-38 and 42 stand rejected as being unpatentable over Eichelburg in view of Jans. The Office contends that Jans teaches a chewable tablet having a hardness of 100 Newtons, not disclosed by Eichelburg. From this, the Office concludes that it would have been obvious to combine Eichelburg and Jans to arrive at the claimed invention because the references teach the advantageous results in the use of "similar ingredients" to obtain an improved palatability composition for companion animals. 03/23/2004 Final Office Action, page 7. Applicants disagree.

As discussed above, the Office admits that Eichelburg does not disclose artificial beef. The compositions in Jans "always contain large amounts of brewer's yeast." Col 1., lines 66-67. The compositions of the present invention do not always contain yeast. The references do not have "similar ingredients." This rejection should not be allowed to stand against at least claims 1-6, and 9-10 because said claims contain artificial beef as the palatable agent. The references

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do not concern and do not motivate or suggest the claimed invention wherein the palatable agent is artificial beef.

Regarding the remaining rejected claims, the compositions in Jans have yeast in addition to a flavouring agent. The broadest range of yeast found by Applicant in Jans is 40% to 70%. Col 4, line 65. The preferred compositions comprise by weight based on the total weight of the composition. flubendazole: from 22% to 33%; brewer's yeast: from 50% to 65%; hydroxypropyl methylcellulose: from 2% to 3% and flavouring agents: from 0.1% to 0.2%. Jans, Col 3, lines 14-20.


As previously discussed, Eichelburg discloses the need for more yeast when admixing with the active ingredient. Although several ranges are provided in Eichelburg (col 11, lines 27-45), Example 2 indicates that the amount is high in an admixture (0.25 oz yeast and 0.0125 oz piperazine adipate). The percent of yeast for coating is 12% and 10% by weight for Examples 1 and 3, respectively.

The pending application has yeast being from about 2% to about 25% by weight. The combined references teach away from this percent of yeast or yeast hydrosolysate in the pending application. Although the word yeast may appear in the references, the references, taken as a whole, teach away from the claimed invention. Furthermore, the general discussions within the references do not suggest or motivate one of ordinary skill in the art to combine them to result in the invention claimed in the pending application.

For at least the above reasons, the pending claims are not rendered obvious by any of the cited references. Withdrawal of the § 103(a) rejections of the claims is therefore respectfully requested.

Conclusion

Applicants submit that the claims are in condition for allowance. Notice to this effect is respectfully solicited. Should the Examiner believe a discussion of this matter would be helpful, the Examiner is invited to telephone the undersigned at (269) 833-7914.


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